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(56) Publications used in the evaluation of patentability:

DE 32 13 434 C1
DE 36 26 549 A1
DE 35 22 196 A1
US 47 59 350
US 46 50 490

Company prospect 97-5110-102 20 MA of the Zimmer, Inc. company, edition 1989 "MG II TOTAL KNEE SYSTEM SURGICAL TECHNIQUE"

(54) Method for the Production of an Endoprosthesis as Joint Replacement for Knee Joints

(57) A method for the production of an endoprosthesis as joint replacement for knee joints, whereby the prosthesis presupposes an operative intervention on the femur, the tibia and the patella of a damaged knee joint, consisting of the stages:

a) Production of a preoperative image of the damaged the joint;

b) Correction of the preoperative image of the damaged knee joint as regards an

approximation to the contours at least on the femur and the tibia that are present in a healthy knee joint;

c) Production of a postoperative image of the damaged knee joint;

d) Opposing the corrected preoperative image and the postoperative image of the damaged knee joint on a comparison image for determining the difference between the two images of the damaged knee joints; and

e) Production of at least one femoral and one tibial component of an endoprosthesis based on the differences of the corresponding contours of femur and tibia determined with the comparison image in the corrected preoperative image and in the postoperative image of the damaged knee joint.

Specification

The invention relates to a method for the production of an endoprosthesis as joint replacement for knee joints, whereby the prosthesis presupposes an operative intervention on the femur, the tibia and the patella of a damaged knee joint.

The operative intervention on a knee joint is considered by the treating physician when the patient complains about severe knee pain and problems as a consequence, for example, of a rheumatic arthritis or also of other joint diseases. The operative intervention traditionally takes place in a plurality of stages that are exclusively adapted to the shaping of joint form parts that are made available industrially in various graduated sizes and that in the final analysis experience such a fastening to milled surfaces, primarily of the front femoral condylus, of the distal femur, of the proximal tibia and of the patella that a vertical alignment to an axis is obtained with such components that is obtained, for example, by a preoperative x-ray film and a marrow nail alignment system for the straight connection line between the hip center, the knee and the foot ankle. An illustrative representation of such an operative procedure is found, for example, in the company prospect 97-5110-102 20 MA of the Zimmer, Inc. company, edition 1989 "MG II TOTAL KNEE SYSTEM SURGICAL TECHNIQUE" as well as in US 4 759 350, in which a relevant marrow nail system is described.

The implantation of such three-part knee joint endoprostheses is not only very expensive but in particular, taking into account the quite different physique of the patients which frequently is present, in any case only an approximate reestablishing of the conditions of a healthy knee joint are obtained with it. Therefore, complications also frequently occur that can be primarily traced to the mechanics of the implanted prosthetic components and thus result, for example, in a pain syndrome of the front knee joint caused by a poor sliding of the of the kneecap with a non-physiological strain on the kneecap sliding joint of the thigh. Also, irritated states, occasionally with

significant hypertrophy a of the mucous membrane of the joint and pronounced effusions in the knee joint frequently result as a consequence of a massive attrition of the implanted prosthetic parts, that partially consist of polyethylene and can also produce an unfavorable sliding behavior with this material if such an attrition becomes too great or a loosening of the osseous anchoring of the component parts of the prostheses occurs, which anchoring is usually performed with pins and a screwing and frequently with a cementing. When such complications are determined the implantation of a new endoprosthesis must frequently be made, whereby new problems result, for example, regarding the creation of a changed support for the components of a new prosthesis with the requirement of a resection of other osseous parts.

DE 32 13 434 C1 teaches a method for the production of endoprostheses or implants that are individually shaped in a multidimensional manner, in which method a start is made from the production of several true-to-scale areal images by computer tomography of the particular body part to be provided with an endoprosthesis or an implant. The area to be occupied by the prosthesis is then detected in the individual images and stored with areal data, whereupon a spatial combination of the image areas takes place using such stored areal data and then a checking and modification of the values of the spatial combination follows in accordance with certain given criteria in order to finally produce the particular endoprosthesis or the implant, for example, by an eroding of a blank or alternatively also by a copy milling with such checked and modified stored combination values. It is indicated as an advantage of this method that the prostheses and implants produced with it are closely adapted over their entire osseous anchoring area to the supporting bone, and in the case of joint endoprostheses a close adaptation regarding the articulating joint surface areas individually to an adjacent bone or to the joint countersurface can be obtained.

DE 36 26 549 A1 teaches a method for the production of an endoprosthesis based on a bone model produced with computer tomography which method is supposed

to be suited in particular for shaft prostheses that are to be adapted to found osseous areas, as well as for bone parts to be replaced that are to be adapted to remaining osseous areas. In this method a reference model is worked with that is produced at first for appropriate osseous areas either of the other, symmetric body half and by a mirroring, or also in accordance with an average model that is adapted with statistical average values to the body size and to the remaining constitution. Thereafter, the surfaces of the three-dimensional model generated by computer tomography and present represented by data and the surfaces of such a reference model are compared by a comparison in an appropriate spatial alignment with one another and at least one area is determined in this comparison in which deviations from the reference model result, whereupon such deviating areas are then replaced by the corresponding areas of the reference model, so that finally the endoprosthesis can be produced in accordance with the model obtained in this manner. The production is realized here in particular by a copy milling of blanks that coincide with the three-dimensional models detected according to the data.

The invention is based on the problem of making a method available for the production of an endoprosthesis as joint replacement for knee joints, which method helps to minimize the complications that can be determined in the traditional implantation of such endoprostheses, taking into consideration the operative intervention on the knee joint that was initially explained in detail, which complications are, for example, the non-physiological joint stress, the problem of a sufficient anchoring possibility in particular of the femoral and tibial prosthetic components and the avoidance of too great a bone loss primarily in a first-time implantation of such an endoprosthesis as joint replacement for knee joints.

This problem is solved by a method for the production of an endoprosthesis as joint replacement, in particular for knee joints, in accordance with Claim 1. Further method features result from the subclaims. The following stages are used:

1. A preoperative image of the damaged knee joint of the patient is produced. The production of such an image can be made by computer tomography, that is, a cross-sectional image method, or preferably by nuclear magnetic tomography, because an especially sharp delineation of the joint contour is possible with it by visualization of the cartilage tissue and/or other soft parts of the damaged knee joint and therewith also a correspondingly optimal prerequisite for the operative intervention is created.

2. Following the production of such a preoperative image the operative intervention is performed on the femur, the tibia and the patella of the damaged knee joint. In this operative intervention basically only a complete removal of the bone which can not support is to take place, and in addition, the removal of only an absolute minimum of the adjacent, healthy bone at least on the femur and the tibia, so that a resection surface is obtained on the bone that is ideal for a later cementing of the associated femoral and tibial component of the endoprosthesis to be implanted.

3. When the operative intervention is finished, an appropriate postoperative image of the knee joint is produced, again either by computer tomography or preferably by nuclear magnetic tomography.

4. Following this operative intervention or also already following the production of the preoperative image of the damaged knee joint a correction of this preoperative image is made, whereby an approximation to the conditions present in a healthy knee joint is sought with this correction. This correction of the preoperative image can be carried out either manually on this preoperative image itself, whereby, therefore, the more or less ideal contours of at least the femur and of the tibia are followed with the correction which contours yield a correspondingly optimal physiological joint contour of the knee joint for the joint

surfaces made available with the endoprosthesis that is implanted later. This correction of the preoperative image can therefore also be alternatively brought about taking an image as base that is a mirror image recording, to the extent still possible, of a healthy knee joint opposite the damaged knee joint, whereby it is assumed for this that the two knee joints of a patient are equally constructed and therefore the most favorable prerequisites for the implanting of the endoprosthesis can actually be taken as base for the damaged joint by means of such a comparison of a damaged knee joint with a healthy one. In addition, it is basically also conceivable that the correction of the preoperative image is performed by a comparison with images of knee joints that were taken under comparable conditions, whereby the knee joints have joint surfaces of femur, tibia and patella that are comparable to the damaged knee joint.

5. The preoperative image corrected in this manner is then compared with the postoperative image produced following the operative intervention in order to determine the differences between the two images. In particular, the conditions on the contours of the femur and the tibia are of interest since the difference in size of these contours results in the basis for the subsequent production of appropriate femoral and tibial components of the endoprosthesis.

6. As indicated above, the last method step of the production of an endoprosthesis as joint replacement in knee joints therefore concerns the production of at least femoral and tibial components that corresponds to the size differences of the surfaces that were determined with the comparison image that were taken for the femur and the tibia for the corrected, preoperative conditions. The production of such femoral and tibial components of an endoprosthesis that is subsequently to be implanted can take place, for example, in that the comparison image detecting the differences between the corrected, preoperative image and the

postoperative image is digitized and thus used for a machine production of the components in a copy method.

As result of the method for the production of an endoprosthesis as joint replacement for knee joints, components are obtained which therefore have the contours of the healthy knee joint or in any case result in slightly different joint contours adapted to the actual bone-soft tissue conditions and resulting in physiologically at the same time corresponding, ideally adapted joint contours, the successful implantation of which is then only more or less dependent on the quality of the anchoring of the components. Because the danger of a rather large mechanical loosening is hardly to be expected for the implantation of such almost ideal joint replacement components, ideally a cement-free anchoring of the components to the femur and to the tibia presents itself for their anchoring, whereby as regards the individual adaptation of the joint conditions in a patient the operative intervention on the damaged knee joint can be carried out regarding the additional removal of healthy bone in addition to the complete removal of bone which can no longer support in such a manner that a physiologically unobjectionable anchoring of the components of the endoprosthesis is obtained for the implantation.

To the extent required, the production of an endoprosthesis will of course also include the production of a component used for the patella of the damaged knee joint. In addition, the method can also be used for operative intervention on other joints, for example, also on the ankle joint, to the extent that comparable conditions can be assumed.

Claims

1. A method for the production of an endoprosthesis as joint replacement for knee joints, whereby the prosthesis presupposes an operative intervention on the femur, the tibia and the patella of a damaged knee joint, consisting of the stages:

a) Production of a preoperative image of the damaged the joint;

b) Correction of the preoperative image of the damaged knee joint as regards an approximation to the contours that are present in a healthy knee joint at least on the femur and the tibia;

c) Production of a postoperative image of the damaged knee joint;

d) Opposing the corrected preoperative image and the postoperative image of the damaged knee joint on a comparison image for determining the difference between the two images of the damaged knee joints; and

e) Production of at least one femoral and one tibial component of an endoprosthesis based on the differences of the corresponding contours of femur and tibia determined with the comparison image in the corrected preoperative image and in the postoperative image of the damaged knee joint.

2. The method according to Claim 1, in which the images of the damaged knee joint are produced with computer tomography or by nuclear magnetic tomography.

3. The method according to Claim 1 or 2, in which the correction of the preoperative image is made manually.

4. The method according to one of Claims 1 to 3, in which the correction of the preoperative image is made with the image of a mirror image photograph of a healthy knee joint of the patient opposite the damaged knee joint.

5 The method according to one of Claims 1 to 4, in which the correction of the preoperative image is made by a comparison of healthy knee joints in which contours comparable to the preoperative image of the damaged knee joint are present on the joint surfaces at least of the femur and of the tibia.

6. The method according to one of Claims 1 to 5, in which the comparison image is digitized and used for the machine production of the femoral and tibial components of the endoprosthesis in a copy method.

PARK
IP TRANSLATIONS

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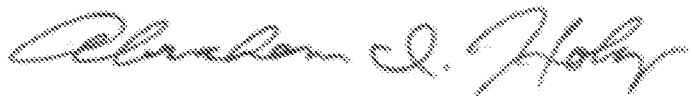
Certification

Park IP Translations

This is to certify that the attached translation is, to the best of my knowledge and belief, a true and accurate translation from German into English of: German Patent Office Number DE 44 34 539 C2.



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